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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,884	01/22/2004	John R. Boehringer	BCLO-100US	5451
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RATNERPRESTIA			EXAMINER	
P O BOX 980			TYSON, MELANIE RUANO	
VALLEY FORGE, PA 19482-0980				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/762,884

**Applicant(s)**

BOEHRINGER ET AL.

**Examiner**

Melanie Tyson

**Art Unit**

3773

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18, 27, 28 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 27 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 June 2008 has been entered. Claim 28 remains withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation "said shaft" in lines 2-4. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Solar et al. (5,947,983). Solar discloses a device for aiding in the closure of a wound for use with at least one suture (see entire document) comprising an external member (110) having a tubular shape with closed circumferential ends (for example, see Figure 1A), at least one aperture (111) extending radially from a first outer wall through and to a second inner wall, and a longitudinally extending aperture (aperture in which element 120 is inserted), an internal member (needle 140) rotatably coupled to the external member along an inner track (122) and having at least one receiver (144) for receiving the suture, wherein the device is capable of being placed within the wound being closed (for example, see Figure 2D).

5. Claims 27 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosmetto et al. (5,127,412). Cosmetto discloses a device for use with sutures to repair a wound of a patient (see entire document) comprising a tubular body (30) having spaced apart apertures (35) as claimed, a shaft (40) rotatably coupled to the tubular body having spaced apart apertures (41) in line with the apertures of the tubular body, and a means for retaining the shaft within the body (for example, see Figures 17 and 18; first end portion 45 against a bearing portion 42, and a second end portion 49 against an end portion 42), wherein the device is capable of being placed within the wound if one desired to do so. The means for retaining is formed such that the shaft

remains within the tubular body in response to a lateral tension when the lateral tension is applied from left to right and from front to back (for example, see Figure 18).

6. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. (3,650,274). Edwards discloses a device for use with sutures to repair a wound of a patient (see entire document) comprising an external member having at least one aperture (16) as claimed, an internal member (20) rotatably coupled to external member having at least one receiver (24) for receiving a suture (30), and a means for retaining the shaft within the member (for example, see Figures 2 and 8; first bottom end portion against a bearing portion 26, and a second top end portion 23 against a top end portion 14), wherein the device is capable of being placed within the wound if one desired to do so.

7. Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (2003/0229361 A1). Jackson discloses a device for use with sutures to repair a wound of a patient (see entire document) comprising an external member (12) having at least one aperture (13) as claimed, an internal member (14) rotatably coupled to the external member having at least one receiver (15) for receiving a suture (20 or 22), and a means for retaining the shaft within the member (for example, see Figures 1 and 2; head portion of 14 against a top surface of 12, and a second bottom end portion of 14 against a bottom end portion of 12), wherein the device is capable of being placed within the wound if one desired to do so.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 1-7, 13-15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al.

Edwards discloses a device for aiding in the closure of a wound (see entire document) comprising an external member (or body) having closed ends, at least one aperture (16) as claimed, and an aperture (15) extending longitudinally (up and down), an internal member (or shaft 20) rotatably coupled to the body having a plurality of apertures (or receivers 24; spaced apart from each other by the center bore) extending radially through the shaft from an outer wall to the inner wall aligned with the at least one aperture in the body for receiving a suture (30), and a means for preventing the shaft from rotating in a direction opposite the first direction (pins 25), wherein the device is capable of being placed within the wound if one desired to do so. Edwards further

discloses the internal member is adapted to rotate in a first direction to wind the suture at least partially around an exterior surface of the internal member (for example, see Figure 3) and the body further comprises a coupling (outer end surfaces) and an orifice (17) and the shaft has an orifice (center bore) coupled to the external member which is connected to the coupling all of which are capable of coupling to a vacuum source to provide vacuum to the wound if one desired to do so. Regarding claims 17 and 18, the device is capable of being used in a human or an animal.

Edwards fails to disclose the external member has a tubular shape. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the external member, since the applicant has not disclosed that a tubular shape provides an advantage, is used for a particular purpose, or solves a stated problem and it appears the prior art rectangular shape would perform equally well.

10. Claims 8-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards in view of Westcott (6,120,525).

Edwards discloses the claimed invention except for a means for applying a rotational force to the shaft with respect to the body. Westcott discloses a device for use with sutures to repair a wound of a patient (see entire document) comprising a tubular body (120) and a rotating shaft (136). Westcott discloses a means for applying a rotational force to the shaft with respect to the body (crank 160 and opening 152 in the shaft). Westcott further discloses the means may comprise a coil spring such that the shaft is driven in a first direction by the coil spring, thus preventing rotation in the

opposite direction, in which the tension may be released by simply moving the coil in the opposite direction such that it is no longer wound-up to further drive rotation of the shaft (for example, see column 3, lines 23-27 and column 7, lines 37-41). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Edwards' device with a crank and opening or a coil spring as taught by Westcott. Doing so would ensure the correct amount of tension is applied to the wound, thus enhancing healing.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant's amendment filed 17 June 2008, with respect to the 35 USC § 112 rejection of claims 1-18, 27, and 34 has been fully considered. The amendment overcomes the 35 USC § 112 rejection. Therefore, the rejection has been withdrawn.

13. Applicant's arguments filed 17 June 2008 with respect to claims 27 and 34 have been fully considered but they are not persuasive. Applicant argues the prior art fails to disclose or teach each and every element as claimed. Examiner respectfully disagrees.

Applicant argues that Cosmetto fails to disclose or suggest a means for retaining the shaft within the tubular body such that the shaft remains within the tubular body in response to a lateral tension exerted on the shaft. It is the examiner's position that Cosmetto discloses a means for retaining the shaft within the body (for example, see



Figures 17 and 18; first end portion 45 against a bearing portion 42, and a second end portion 49 against an end portion 42), wherein the means for retaining is formed such that the shaft remains within the tubular body in response to a lateral tension when the lateral tension is applied from left to right and from front to back (for example, see Figure 18).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

August 28, 2008